

SEP 22 2005

K051629

**510(K) SUMMARY**  
**(as required by 807.92(C))**

Submitter of 510(K): Blease Medical Equipment Ltd.  
Deansway, Chesham  
Bucks, England HP5 2NX

Phone +44 1494784422  
Fax +44 1494 791497

Contact Person: Richard Cooke

Date of Summary: Monday, 19 September 2005

Trade Name: Blease Frontline Sirius 2000, 3000

Classification Code: BSZ

Classification Name: Anaesthesia Gas Machine

Predicate Device: Blease Frontline Sirius K041430

Device Description/  
Comparison:

The Frontline Sirius with 8700 ventilator is similar to the cleared Frontline Sirius anaesthesia machine with the 6200 ventilator. The size and shape of the cabinet are identical, but the pneumatic systems are the same. The ventilator user interface is now graphical with colour LCD and Trak wheel control.

Intended Use:

The Blease Frontline Sirius Range, Anaesthesia Machines are intended for use in the hospital environment and operating room. It may be used for the delivery of oxygen, air, and nitrous oxide in a controlled manner to various patient breathing circuits with or without the use of a mechanical ventilator, and may be used for the delivery of anaesthetic vapour by use of a dismountable vaporizer. The device is intended for use only by a suitably qualified physician.

## Test and Validation

The system has been validated by testing to all relevant US standards covering operation, Safety, EMC.

Full performance testing and validation to the Blease product, software, manufacturing and engineering specification has been carried out with satisfactory results using traceable calibrated test equipment.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 22 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Blease USA, Incorporated  
C/O Mr. Arthur J. Ward  
AJW Technology Consultants, Incorporated  
962 Allegro Lane  
Apollo Beach, Florida 33572

Re: K051629  
Trade/Device Name: Blease Frontline Sirius Range Anaesthesia Machines  
Regulation Number: 21 CFR 868.5160  
Regulation Name: Gas Machine for Anesthesia or Analgesia  
Regulatory Class: II  
Product Code: BSZ  
Dated: September 8, 2005  
Received: September 12, 2005

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K051629

DEVICE NAME: Blease Frontline Sirius Range Anaesthesia Machines

INDICATIONS FOR USE:

The Blease Frontline Sirius Range, Anaesthesia Machines are intended for use in the hospital environment and operating room. It may be used for the delivery of oxygen, air, and nitrous oxide in a controlled manner to various patient breathing circuits with or without the use of a mechanical ventilator, and may be used for the delivery of anaesthetic vapour by use of a dismountable vaporizer.

The device is intended for use only by a suitably qualified physician.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE  
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)

Division of, Anesthesiology, General Hospital, Infection Control and Dental Devices

Prescription Use YES

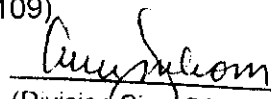
OR

Over The Counter -

Use \_\_\_\_\_

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

  
(Division Sign Off)

Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number:

K051629